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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,447	12/30/2004	Makoto Ogino	Q85576	4830

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EXAMINER	
SCHLAPKOHL, WALTER	

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1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,447	OGINO ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	WAS

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/06 and 12/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the papers filed 4/20/2007. Claims 1-9 are pending. Claims 1-7 are withdrawn. Claims 8-9 are under examination in the instant Office action.

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 4/20/2007 is acknowledged.

Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/2007.

The restriction requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

Receipt of the IDS documents filed 12/30/2004 and 3/27/2006 is acknowledged. Initialed and signed copies of the IDS documents are attached hereto.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a sequence listing in paper form and in computer readable form was filed after the filing date of PCT/JP03/08367 (7-1-03), but no statement accompanied the sequence listing indicating that the sequence listing did not comprise new matter. Applicants are required to comply with all of the requirements of 37 C.F.R. 1.821 - 1.825. Any response to this Office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Claim Objections

Claim 9 is objected to because of the following informalities: claim 9 comprises non-elected subject matter as the claim is drawn to claims 5-7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 8 recites "[a] screening method for an agent for improving insulin resistance, comprising

i) a step of allowing a cell transformed with a reporter gene fused with the promoter region of p68 RNA helicase represented by SEQ ID NO:5 to contact with a test substance, and

ii) a step of analyzing the change of the test substance-dependent transcription induction activity, in which the expression of the reporter gene is used as an index" in lines 1-10 (emphasis added). Claim 8 is vague and indefinite in that the metes and bounds of "the promoter region of p68 helicase represented by SEQ ID NO:5" are unclear. Which sequences does Applicant consider to be "represented" by SEQ ID NO:5? Those with similar activity? Those with a particular degree of homology? Furthermore, based upon a comparison of Applicant's

disclosed SEQ ID NO:5 and the promoter region disclosed by Rössler et al (*Nucleic Acids Research* **28**(4):932-939, 2000; IDS Reference) SEQ ID NO:5 appears to encompass nucleotides after the transcription start site, i.e. non-promoter sequences.

Claim 9 recites "[a] method for producing a pharmaceutical composition for improving insulin resistance, comprising

a screening step using the screening method according to one of claims 5 to 8, and

a formulation step using a substance obtainable by said screening" in lines 1-6 (emphasis added). Claim 9 is vague and indefinite in that the metes and bounds of "a formulation step using a substance obtainable by said screening" are unclear. Without any indication of the structure of the substance obtainable by said screening method, it is unclear what the metes and bounds for a "formulation step" requiring the use of such a substance are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph,

as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Note: for purposes of this rejection only, Examiner has interpreted claim 8 to be drawn to a screening method comprising the use of a cell transformed with a reporter gene fused to the p68 RNA helicase promoter comprising a portion of SEQ ID NO:5 comprising nucleotides from -1164 to the transcription start site of SEQ ID NO:5, wherein said cell is allowed to contact a test substance and a change in reporter gene expression in response to the test substance is analyzed and used as a index of the test substance's ability to improve insulin resistance. Furthermore, Examiner has interpreted claim 9 to be drawn to methods for producing a pharmaceutical composition for improving insulin resistance, comprising a set of screening steps according to claim 8, as well as a formulation step for producing a substance obtainable by said screening method.

The claim is drawn to methods of screening agents for improving insulin resistance wherein a cell transformed with a reporter gene fused to the promoter region of p68 RNA helicase

represented by SEQ ID NO:5 is allowed to come into contact with a test substance and a change in test substance-dependent transcription is determined by analyzing reporter gene expression. The claim is further drawn to such a method wherein a substance obtainable by such screening is formulated or produced. The claims do not provide any structural information with regard to the substances obtainable by said screening. Nor do the claims provide any guidance with regard to how such substances may be formulated or produced. Thus, the rejected claims comprise a set of substances that are defined by their function only, i.e., by their ability to be obtained in the recited screening method(s).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing and/or identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes the construction of two reporter constructs, pGL3-p68-899bp and pGL3-p68-1184bp which would appear to comprise the promoter region of p68 RNA helicase up to the -1164 and -899 bp, respectively (see paragraph bridging pages 42-43). The

specification further describes the use of these reporter constructs to test p68 RNA helicase promoter activity in COS-1 cells in the presence and absence of pioglitazone, a PPARγ ligand known to improve insulin resistance (see paragraph bridging pages 6-7 and Example 2 at page 37). It was determined that pioglitazone increases p68 RNA helicase promoter activity and this information, along with p68 RNA helicase's ability to bind PPARγ, allowed Applicant to conclude that "…the induction of PPAR-interactive p68 RNA helicase expression can be used for screening a new type of pharmaceutical agent which is different from PPARγ synthetic ligands as a conventional agent for improving insulin resistance" (see page 46, last paragraph). Finally, the specification teaches that "[a]dditionally, a pharmaceutical composition for improving insulin resistance can be produced by using a substance obtainable by the screening method of the present invention as the active ingredient and using a carrier, an excipient and/or other additives for preparation" (see page 47, 1st full paragraph).

No description is provided of a single compound, much less a single pharmaceutical composition, identified by such a method except for pioglitazone, and pioglitazone was already known to improve insulin resistance. Claim 9 is a reach-through claim because the claimed invention is drawn to a method of

formulating/producing a genus of pharmaceutical compositions/substances obtainable by the screening method of claim 8, but no examples of such compounds or structures characteristic of such compounds are disclosed (except for one compound which was already known to improve insulin resistance: pioglitazone). Furthermore, in order to evidence possession of the claimed method, one would need to demonstrate possession of its process steps which require the use of such pharmaceutical compositions/substances for their formulation.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claim with regard to structure and function, the examples are only representative of one compound identified by such a method and is not representative of a method step wherein such a compound is formulated/produced. The results are not necessarily predictive of any other pharmaceutical compositions/substances which are obtainable from the screening method according to claim 8. Thus, it is impossible to extrapolate from the example described in the specification those pharmaceutical compositions/substances identified by the recited screening methods that would necessarily meet the structural/functional characteristics of the rejected claim, i.e. that would be

capable of being produced as a pharmaceutical composition for improving insulin resistance.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of pharmaceutical compositions/substances obtained by a method of screening for agents which improve insulin resistance comprising the use of a cell transformed with a reporter gene fused to the p68 RNA helicase promoter comprising a portion of SEQ ID NO:5 comprising nucleotides from -1164 to the transcription start site, wherein said cell is allowed to contact a test substance and a change in test substance-dependent expression is analyzed and used as an index of the test substance's ability to improve insulin resistance. Furthermore, the prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of methods for producing a pharmaceutical composition/substance obtainable by such a screening method, wherein the methods comprise a formulation step for producing said substance such that the substance can be used as a pharmaceutical composition for improving insulin resistance. Rössler et al (*Nucleic Acids Research* **28**(4):932-939, 2000; IDS Reference), disclose methods comprising the use of DNA fragments of the p68 RNA helicase promoter to determine the promoter's ability to direct the transient expression of

chloramphenicol acetyltransferase in 293 cells, but Rössler et al did not test the promoter's activity against different test compounds to see whether the compound could affect reporter gene expression such that the compound could be identified as an agent for improving insulin resistance. Furthermore, the promoter sequence disclosed by Rössler et al appears to be slightly different from that of SEQ ID NO:5 (see, e.g., TATA box sequence as disclosed by Rössler et al in Figure 3A compared to that present in SEQ ID NO:5).

Given the very large genus of potential pharmaceutical compositions/substances capable of being obtained by such methods and given the limited description provided by the prior art and specification with regard to such pharmaceutical compositions/substances capable of fulfilling the claim limitations of claim 9, the skilled artisan would not have been able to describe the broadly claimed genus of pharmaceutical compositions/substances which are capable of improving insulin resistance as identified by the screening method of claim 8. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those pharmaceutical compositions/substances that satisfy the functional limitations of the claim. Therefore, the skilled artisan would have reasonably concluded Applicant was

not in possession of the claimed invention for claim 9.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

July 16, 2007

/Nancy T. Vogel/
Primary Examiner, Art Unit 1636